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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,448	08/30/2001	Jin-Ho Lim	A-70899/RFT	2849

7590

05/17/2004

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EXAMINER

WOITACH, JOSEPH T

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM

Office Action Summary**Application No.**

09/944,448

Applicant(s)

LIM ET AL.

Examiner

Joseph T. Weitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-10,13,14,32 and 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-10,13,14,32 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This application filed August 30, 2001 claims benefit to foreign applications: 2000-50881, filed August 30, 2000; 2000-65629, filed November 6, 2000; and 2001-12485, filed March 10, 2001 each filed in Korea.

Applicants' amendment filed March 8, 2004, has been received and entered. The specification has been amended. Claims 2, 11, 12, 15-31 have been canceled. Claims 1, 3-10, 13 and 14 have been amended. Claims 32 and 33 have been added. Claims 1, 3-10, 13, 14 and 32-33 are pending and currently under examination.

Election/Restriction

Applicant's election of group I, claims 1-14 and 25 in Paper No. 8 (and previously in paper number 6) was acknowledged. Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The amendment to the claims to include a step of isolating the inner cell mass cells by removing the trophectoderm through the use of anti-human lymphocyte antibodies encompasses the invention restricted to non-elected Groups III and IV. In this case, the Examiner finds that it would not constitute an undue burden to exam the new limitation in the context of establishing embryonic stem cells from ICM cells isolated through the use of anti-human lymphocyte antibody. Therefore, groups I, III and IV are rejoined, because group III drawn to a method of isolating ICM cells with the use an anti-human

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lymphocyte antibody and group IV is drawn to a method of generating embryonic stem cells from ICM cells is encompassed by the instantly claimed method.

Claims 1, 3-10, 13, 14, 32 and 33 are currently under examination as they are drawn to a method of establishing undifferentiated human embryonic stem cells in culture and the isolated undifferentiated human embryonic stem cells.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

The application is in compliance with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825.

The submission of a sequence listing, CFR, declaration by attorney (page 7) and amendments to the specification have addressed the basis of the objection.

Claim Objections

Claim 13 is objected to because of the following informalities: Claim 13 has been amended to recite "of anyone of the preceding claims", however because the ordering and

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number of claims may be subject to change upon allowance it is suggested that the claim be amended to specifically refer to the method claims on which it depends.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-10, 13 and 14 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for culturing the inner mass cells of a blastocyst embryo to establish embryonic stem cells, does not reasonably provide enablement for culturing any part of the blastocyst embryo is withdrawn.

The amendment to claim 1 to recite that the inner cell mass cell is cultured into an embryonic stem cell has addressed the basis of the rejection. Moreover, the newly added step of treating the embryo to remove the cells of the trophectoderm effectively removes the other cell type present in the embryo leaving only the inner cell mass cells.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-10, 13 and 14 previously rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

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Applicants' comments (Applicants' amendment page 8), the support in the specification (page 11, lines 20-25) and the amendment to delete claim 2 has addressed the basis of the rejection.

Newly amended claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the preamble of the claim has been amended to recite a "process for making undifferentiated human' however the method only results in establishing embryonic stem cells not a human. The claim is unclear if further steps are required or the claim is limited to the cells provided in the last step. Amending the preamble of the claim to reflect the final step of the method would obviate the basis of the rejection.

Claims 1, 3-10, 14, 32 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claims 1 and 14 have been amended to indicate that the trophectoderm is removed to isolate the inner cell mass, however the specification only supports the use of anti-human lymphocyte antibodies and complement to selectively destroy the cells of the trophoderm. The isolation of the inner mass cell from the resulting cells and debris requires additional steps. The claim vague because what is encompassed in practicing the newly added limitation is not clearly set forth. More clearly detailing how to perform the isolation of the inner cell mass would obviate the basis of the rejection.

Newly amended claim13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention. Specifically, the amendment to the claim to encompass 'any one of the preceding claims' is unclear because the method claims include dependent claims that follow claim 13, i.e. claims 32 and 33, and it is not clear if claim 13 includes these claims because they do not numerically precede claim 13. It is unclear if this limitation includes only claims numerically before 13 or any claim that when renumbered or reordered would precede the claim. More clearly indicating the specific claim numbers encompassed by the claim would obviate the basis of the rejection.

Claim Rejections - 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Thomson (1998- IDS reference).

Claim 13 encompasses an undifferentiated human embryonic stem cell formed by the method of any of the proceeding claims. It is noted that the courts have stated that "When the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent." See MPEP 2112.01 or *In re Best*, 195 USPQ 430, 433 (CCPA 1997). In this case, while the embryonic stem cells are obtained from the method of claim 24, they are not materially different from an embryonic stem cell obtained by any other

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means. Thomson teaches the isolation and characterization of human embryonic stem cells.

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on "inherency" under 35 USC 102,, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

In the instant case Thomson teaches human embryonic stem cell lines in culture. It is noted that though the methods taught by Thomson are similar to those claimed, they are not identical to that of claims 1, 3-10. However, each result in an undifferentiated embryonic stem cell that can be maintained in culture under the appropriate conditions.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-10, 13 and 14 rejected under 35 U.S.C. 103(a) as being unpatentable over Thomson (1998- IDS reference) with Kaufmann *et al.* Fert. Steril ((1995) 64:1125-1129) is withdrawn.

Amendments to the claims to include the step of removing the cells of the trophectoderm using anti-human lymphocyte antibody has differentiated the claimed invention from that made obvious by Thomson and Kaufmann *et al.*

It is noted that Thomson teaches that anti-human antibodies were used to isolate ICM cells to establish ES cell lines (see page 1147, References and Notes number 6 and 26), however the antibodies used by Thomson were generated against BeWo cells which is a human choriocarcinoma cell line (a transformed trophoblast cell line), not against a lymphocyte.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Fassler *et al.* JCB 128:979-988 (May 2004) ;

Spielmann *et al.* J Ebryol Exp Morphol 60:255-269 (Dec 1980);

Stojkovic *et al.* Anim Reprod Sci 50(1-2):1-9 (Feb 27 1998) ; and

US Patent application 2003/0157710.

Each of the above reference provide further evidence that the use of antibodies and complement during to remove the trophectoderm were well known and used in the art to isolate inner cell mass cells. However, while various sources of antibody were used none of the

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references of record specifically teach to use an anti-lymphocyte antibody. The instant specification provides the first teaching and reasoning for the use of such an antibody in establishing human embryonic stem cells in culture.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

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